

Dakai Liu and Elazar Rabbani

Serial No. 09/046,833

Filed: March 24, 1998

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April 29, 2008 Office Communication) – May 9, 2008]

REMARKS

Reconsideration of this application is respectfully requested.

Claims 91-117 were previously pending in this application. In the claim listing above, claims 91 and 112 have been amended. No claims have been added or canceled by this paper. Accordingly, as amended above, claims 91-117 are presented for further examination in this application.

Changes To The Claims

As just indicated, Applicants have amended claims 91 and 112 to define their invention more clearly. As now set forth in claim 91, the "sequences for the non-nucleic acid components of said viral vector have been stably integrated in the genome of said cell line and code for envelope *proteins* from two different viruses." In claim 112, the language has been changed to recite "sequences for the non-nucleic acid components of said viral vector have been stably integrated in the genome of said cell line and code for envelope *proteins* from two different viruses. Thus, the term "genes" has been replaced with "proteins" in claims 91 and 112.

The foregoing amendment, actually a word change, is not believed to insert new matter into Applicants' disclosure. Indeed, the Examiner astutely observed in the Office Communication (page 3) that the previous language was "unclear because nucleic acid sequences **code for** polypeptides, not genes." See rejection under 35 U.S.C. §112, second paragraph. Thus, both amendments correct an error in the claim language which is obvious from its context.

Applicants wish to point out that neither of the foregoing amendments raises new issues that would require further consideration and/or search. Moreover, the amendments do not raise the issue of new matter. It is believed that the claim amendments will place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Finally, the amendments to the claims do not

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present additional claims without canceling a corresponding number of finally rejected claims.

Entry of the claim amendments is respectfully requested.

Withdrawn Rejections

Before addressing the two sole remaining grounds for rejection, Applicants appreciate the indication in the Office Communication (page 3) that any rejections not repeated in the Office Action are withdrawn.

The Rejection Under 35 U.S.C. §112, First Paragraph

Claims 91-117 stand rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. According to the Office Communication (pages 2-3):

Applicants have amended claim 91 and presented new claim 112 to recite a viral vector packaging cell line comprising sequences for the non-nucleic acid components of the viral vector wherein said sequences have '[b]een stably integrated in the genome of said cell line and code for **envelope genes** (emphasis added) from two different viruses".

There is no support for the newly claimed limitation in the application, as filed. Applicants, in the instant application, recite packaging cells that comprise sequences encoding envelope or surface components' for viral vectors. Throughout the specification applicants refer to packaging cells for producing enveloped viral vectors comprising two components present on the surface or envelope of the vector wherein the components can be from two different viruses but do not explicitly or implicitly contemplate packaging cells comprising two different genes encoding two different envelopes from two different viruses. This is a NEW MATTER rejection.

The new matter rejection is respectfully traversed.

In response, Applicants point out their specification provides ample support for the present invention and claim language wherein packaging cells comprising two different genes encode two different envelopes from two different viruses. On page 32, first full paragraph, for example, a number of envelope proteins are disclosed:

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The proteins of multitropic vector can be native or non-native to said virus vector. Useful native proteins include the retrovirus ecotropic and amphotropic, polytropic or xenotropic env proteins. Non-native proteins useful for gene delivery to human cells include all of the envelope proteins from human viruses, e.g., gp120 derived from HIV-1 or HIV-2 that can provide tropism for CD4+ cells, env proteins of HTLV I and HTLV II that can provide tropism for T cells, the envelope proteins of hepatitis B virus (HBV) that can provide tropism for liver cells. Envelope proteins from influenza such as HA that can provide tropism to human cells can also be useful. Envelope protein from EBV can also provide tropism for human B cells.

On page 33, first full paragraph, it is disclosed:

For example, a **packaging cell that can produce multitropic retrovirus vectors containing both the ecotropic env protein and an amphotropic, polytropic or xenotropic env protein** can be made from a mouse packaging cell such as 3T3 cells. Such a packaging cell could be constructed by the introduction into the cell of one or more plasmids containing the sequences encoding the packaging components, i.e., gag and pol, and the two envelope proteins. . . . [emphasis added]

Later on page 33, last paragraph, it is further disclosed:

Multitropic virus vectors can also be prepared wherein such viruses are retroviruses that contain in the virus envelope two or more compounds, at least one of which is native to said virus, such as the ecotropic env protein of MMLV, and at least one compound that is non-native to the virus vector but has affinity to the target cell. Such a non-native compound as that can be derived from another virus envelope and further provides affinity for the target cell. For example, a packaging cell that can produce multitropic retrovirus vectors containing both a native ecotropic env protein [for example, the aforementioned MMLV ecotropic env protein] and a non-native protein such as the HIV-1 gp120 can be produced in a mouse packaging cell such as a modified 3T3 cell. [emphasis added]

Thus, Applicants' specification clearly supports the notion of packaging cells comprising two different genes which encode two different envelopes from two different viruses. In view of the above-quoted support, Applicants respectfully request reconsideration and withdrawal of the new matter rejection.

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The Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 91-117 stand rejected for indefiniteness under 35 U.S.C. §112, second paragraph. According to the Office Communication (page 3):

Claims 91 and 112 (and dependent claims) are vague in that they recite a packaging cell line comprising nucleic acid sequences which have been stably integrated into the genome and "code for envelope genes" from two different viruses. This language is unclear because nucleic acid sequences code for polypeptides, not genes.

As indicated earlier, claims 91 and 112 have been amended to recite "envelope *proteins*" instead of the previously recited "envelope genes." As also indicated earlier, both amendments serve to correct an error in the claim language which is clear from its context.

In view of the foregoing amendments, Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection, thereby placing all of claims 91-117 in allowable condition.

Favorable action on this application is respectfully urged.

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SUMMARY AND CONCLUSIONS

Claims 91-117 are presented for further examination. Only claims 91 and 112 have been amended in the claim listing above. No claims have been added or canceled by this paper.

No fee or fees are believed to be due in connection with this Amendment. If any other fee or fees are due, however, The Patent and Trademark is authorized to charge the amount of any such fee(s) to Deposit Account No. 05-1135, and to credit any overpayment thereto.

Applicants respectfully submit that all of the instant claims are in allowable condition. Should it be deemed helpful or necessary, the Examiner is respectfully invited to telephone the undersigned at (212) 583-0100 to discuss the subject application.

Respectfully submitted,



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